IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,	)	
Plaintiff,	)	
v.	)	Civil Action No. 2:08-cv-2141
CEPHALON, INC.,	)	
Defendant.	)	

REPLY OF THIRD-PARTY PHARMACEUTICAL COMPANIES
IN SUPPORT OF MOTION FOR PROTECTIVE ORDER

All interested parties -- including Cephalon, the Federal Trade Commission ("FTC"), the Direct Purchaser Plaintiffs, the Generic Defendants and Apotex -- agree with the Third-Party Pharmaceutical Companies (the "Third Parties")[1] that the confidential materials sought by Cephalon's motion to compel are not relevant to this litigation. Furthermore, as for the FTC's 2002 and 2010 studies that precipitated this dispute, Cephalon agrees they are not relevant, and the FTC stipulates that it will not seek to introduce them into evidence.

[1] The Third Parties are: Abbott Laboratories; Actavis Group hf and Actavis Inc.; Almirall, S.A.; Anchen Pharmaceuticals, Inc.; Astellas Pharma Inc. and Astellas Pharma US, Inc.; AstraZeneca PLC; Bayer Healthcare Pharmaceuticals Inc.; Baxter Healthcare Corporation; Ben Venue Laboratories, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Bristol-Myers Squibb Company; Dr, Reddy's Laboratories Inc.; Endo Pharmaceuticals Holdings Inc.; Esai Inc.; Forest Laboratories, Inc.; Fresenius Medical Care Holdings, Inc.; GlaxoSmithKline plc; Hoffmann-La Roche Inc.; Impax Laboratories, Inc.; Johnson & Johnson; King Pharmaceuticals, Inc.; Lupin Limited and Lupin Pharmaceuticals, Inc.; Merck Sharp & Dohme Corp., formerly known as Merck & Co., Inc.; Novartis Corp. and Novartis Pharmaceuticals Corp.; Paddock Laboratories; Par Pharmaceuticals, Inc.; Pfizer Inc.; Purdue Pharma L.P.; Roxane Laboratories, Inc.; Sandoz Inc.; sanofi-aventis US LLC; Shire LLC; Sunovion Pharmaceuticals, Inc., formerly known as Sepracor, Inc.; Upsher-Smith Laboratories, Inc.; URL Pharma, Inc.; Watson Pharmaceuticals, Inc.; and Wockhardt Limited and Wockhardt USA LLC.

In these circumstances, it would be fundamentally unfair and contrary to common sense if the Third Parties are forced to bear the substantial injury to their commercial and competitive interests that will flow from disclosure of highly sensitive documents that are concededly not relevant to this litigation and that are ostensibly being sought to respond to two FTC studies that will not be in evidence. The governing statutes do not permit this disclosure; and no party has shown why it would be fair or sensible to inflict this injury on the Third Parties. In fact, Cephalon specifically recognizes the "legitimate confidentiality concerns" of the Third Parties, and it has no answer to the Third Parties' argument that disclosure of these confidential materials, even under the protective order, would be highly damaging to the commercial and competitive interests of the Third Parties.

The FTC has not filed an opposition to the Third Parties' Motion for Protective Order. The Motion therefore should be deemed unopposed by the FTC; and the FTC should not be permitted to contest the relief sought by the Third Parties. *See E.E.O.C. v. Eastern Engineered Wood Prods.*, No. 04-CV-04490, 2006 WL 5334849, at *1 n.1 (E.D. Pa. Feb. 27, 2006) (Local Rule 7.1(c) "provides that when a non-moving party fails to respond to a filed motion within the appropriate time period, the court may treat the motion as unopposed and dispose of said motion").

Cephalon has now modified the relief it seeks -- unlike its original demand for "all documents concerning" the FTC's 2002 and 2010 studies, Cephalon's proposed orders submitted with its Opposition seek a statement identifying "the specific conclusions and/or statistics" on which the FTC will rely, "the source materials" for those conclusions and statistics, and "which, if any, of those source materials are confidential documents provided to the FTC by others." However, because Cephalon continues to seek disclosure of the Third Parties' confidential materials filed with the FTC under the Medicare Prescription Drug,

Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2006 (2003), and the Federal Trade Commission Act (the "FTCA"), 15 U.S.C. § 41 *et seq.*, the Third Parties submit this reply in support of their Motion for Protective Order to preclude the disclosure of such materials.[2]

ARGUMENT

1. Cephalon Does Not Answer the Third Parties' Argument that Disclosure of Their Sensitive Documents, Even Under the Protective Order, Would Be Highly Injurious

The Third Parties' Memorandum in Support of the Motion for Protective Order ("Mem.") makes an extensive showing that the documents sought by Cephalon's motion are highly sensitive and proprietary, and that disclosure of those documents would significantly injure the Third Parties' commercial interests. (Mem. at 7-12.) Cephalon's Opposition ("Opp.") does not dispute and indeed acknowledges these "legitimate confidentiality concerns." (Opp. at 2, 13.)

However, Cephalon makes the conclusory assertion that these confidentiality concerns "are addressed by the protective order already in place in this case." (Opp. at 2-3.) But Cephalon disregards and does not answer the Third Parties' essential point that disclosure to outside counsel of their competitors and to plaintiffs' class action counsel -- as provided for under the protective order -- would be highly injurious. (Mem. at 9-11.) Cephalon offers no response to the Third Parties' argument (Mem. at 9-11) that outside counsel and experts could not segregate the information obtained here from other information they use in matters

[2] The Direct Purchaser Plaintiffs have filed a "statement of position" asserting that the Court's decision on the Third Parties' Motion for Protective Order and Cephalon's Motion to Compel should not apply to them. (Dkt. No. 122.) However, the Court's decision with respect to production of the Third Parties' confidential materials will be the law of the case and should be binding on the Direct Purchaser Plaintiffs.

adverse to the Third Parties. Cephalon's silence on this issue tacitly acknowledges the gravity of the concerns raised by the Third Parties about the unfair and unwarranted injury to their interests that would flow from disclosure, even under the terms of the protective order.

2. The MMA and FTCA Bar Disclosure of Materials that Are Not "Relevant"

As addressed in the Third Parties' opening papers, the MMA and FTCA prohibit disclosure of any confidential material that is not "relevant" (or, in the case of the FTCA, "relevant" and "material") to a judicial or administrative proceeding. (Mem. at 4-5, 14.) This is a statutory bar on disclosure of confidential MMA and FTCA material; by the express terms of both statutes, disclosure is barred as a matter of law unless material is "relevant" (or "relevant" and "material"). (Mem. at 4-5, 14.)

Cephalon concedes that the MMA and FTCA material it seeks is neither relevant to this litigation nor proof of any fact in dispute in this litigation. (*See* Opp. at 4-7, 11.) Likewise, the FTC, in its papers opposing Cephalon's motion to compel, endorses Cephalon's position that the requested "materials are 'unrelated' to the investigation that gave rise to this case and are 'irrelevant' to proof of adjudicative facts in this case." (FTC Mem. in Opp. to Motion to Compel ("FTC Mem."), at 1.) The FTC specifically argues that the Third Parties' MMA and FTCA materials do not meet the "threshold standard of relevance." (FTC Mem. at 8).

Where, as here, neither Cephalon nor the FTC advances any argument that the requested MMA and FTCA materials are "relevant" to this litigation, the statutory language clearly and expressly bars disclosure of these confidential materials. (Mem. at 4-5, 14.)

3. The MMA and FTCA Bar Discovery of Confidential Materials by a Private Party

The Third Parties' opening papers demonstrate why private litigants are barred as a matter of law from seeking discovery of confidential materials filed under the MMA and

FTCA. (Mem. at 12-14.) This statutory bar on disclosure of MMA and FTCA materials to private litigants is established by FTC decisions (Mem. at 12), which are binding on this Court as a matter of *Chevron* deference to an agency's reasonable interpretation of the statutory limits of its authority. *See National Railroad Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 417 (1992) ("Judicial deference to reasonable interpretations by an agency of a statute that it administers is a dominant, well-settled principle of federal law.").

Cephalon identifies no basis for ignoring this statutory bar on disclosure. Cephalon relies instead on factual distinctions of the FTC cases. (Opp. at 11-12 & n.9.) But those factual differences have no bearing on the question presented here. The FTC cases establish a legal rule (unaffected by the factual differences Cephalon cites) that a private litigant in the circumstances presented here is not permitted to seek discovery of MMA and FTCA materials. Accordingly, while MMA or FTCA materials related to the modafinil agreements might be discoverable in this case, if the FTC intends to use them as evidence, MMA and FTCA filings involving other drugs, other companies and other settlement agreements that are not at issue in this matter are not subject to discovery by a private litigant as a matter of law.[3]

4. <u>The FTC Will Not "Use" the MMA and FTCA Materials</u>

As the Third Parties demonstrated in their opening brief, the statutory confidentiality protections bar disclosure in the circumstances presented here, where the FTC is not using the Third Parties' MMA and FTCA filings in this litigation. (Mem. at 12-13.) In particular, the FTC stipulates that it will not seek to introduce the 2002 and 2010 studies into

[3] Furthermore, Cephalon offers no authority supporting the proposition that litigation over a given product and a given set of MMA filings -- here, the Provigil MMA filings -- would support disclosure of MMA or FTCA filings made with respect to unrelated products, companies and transactions, even if those were deemed logically relevant.

evidence. (FTC Mem. at 2.) As for the MMA and FTCA materials underlying those studies, the FTC states that it "has not and will not introduce any non-Provigil MMA filings (or information disclosed in such filings) in this proceeding." (FTC Mem. at 15.) Further, the FTC states that it "has not provided its experts with any of the materials underlying either the 2002 or the 2010 study." (FTC Mem. at 12.)

Cephalon nonetheless makes the strained argument that the FTC is "using" the confidential MMA and FTCA materials in this proceeding "every time it chooses to introduce . . . statistics and other conclusions from the [2002 or 2010] studies to influence judicial proceedings." Cephalon's argument does not withstand analysis. The MMA allows disclosure only if the Third Parties' underlying confidential MMA material "actually is used" by the FTC. (Mem. at 12.) But there is no such "actual use" when the materials are not placed in evidence and are not provided to expert witnesses. The concept of "use," in this setting, clearly requires reliance upon the Third Parties' confidential MMA materials as evidence (Mem. at 12-13) -- precisely what the FTC has said it will not do.[4] Likewise, the FTC's non-evidentiary use of its 2002 and 2010 studies -- if permitted at all -- is not an evidentiary use of the underlying MMA materials.

Similarly, the FTCA allows disclosure only if information is compiled "for the purpose of aiding in the prosecution" against a party. (Mem. at 12.) The materials at issue here do not meet that standard -- the FTC has stated explicitly that the requested materials "do not relate to the conduct which gave rise to this action" and "are not part of the Commission's modafinil investigative file." (Mem. at 15 (quoting Ex. 1 at 5).)

---

[4] The issue could be different if the FTC sought to make selective use of confidential MMA and FTCA materials, such as by selectively introducing snippets of such material into evidence or selectively providing such material to its expert witnesses. But that circumstance is not presented here.

5. Cephalon Has Failed to Demonstrate a Need Supporting Disclosure of the Confidential MMA and FTCA Materials

The Third Circuit has recognized that a court "must balance the requesting party's need for the information against the injury that might result" from compelled disclosure. *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 785-86 (3d Cir. 1994). *See also Mannington Mills, Inc. v. Armstrong World Indus., Inc.*, 206 F.R.D. 525, 529 (D. Del. 2002) (non-party need not disclose confidential trade secrets, "even if the information sought is relevant, where . . . the potential harm caused by production outweighs the benefit").

Given the FTC's concessions that it will not "offer the two studies into evidence," that it "has not provided its experts with any of the materials underlying either the 2002 or the 2010 study," and that it "has not and will not introduce any non-Provigil MMA filings (or information disclosed in such filings) in this proceeding" (FTC Mem. at 2, 12, 15), Cephalon cannot demonstrate a need for production of the Third Parties' highly confidential materials. Because the 2002 and 2010 studies will not be in evidence, Cephalon has no need for the underlying MMA and FTCA materials in order to respond to any non-evidentiary reliance that the FTC places on those studies.

In particular, if Cephalon establishes (Opp. at 9-10) that the FTC's reliance on these studies is "adjudicative" and not properly "legislative," the FTC (or its expert witness) could not rely on the studies as factual support because the studies will not be in evidence. Cephalon does not need production of the MMA and FTCA materials to make or support that argument. By the same token, if Cephalon is concerned that the FTC (or its expert) will rely on the studies for estimates regarding the purported consumer costs of certain settlements (Opp. at 6-7), Cephalon can challenge the estimates by showing that this is a factual question that must be proven and supported with evidence. In other words, now that the FTC has clarified that it is not relying on the 2002 and 2010 studies as evidence, there is no need for

Cephalon to disprove those studies on factual grounds. Cephalon instead is free to argue that the FTC (or its expert) is not permitted to rely on those studies as proof of any fact. Or, it can establish through cross-examination or argument that any such "legislative" reliance on these studies is unsupported by evidence.

For the same reason, Cephalon does not need the Third Parties' MMA and FTCA materials to support its argument that the FTC studies were not "conducted by an independent entity on which an expert may ordinarily rely." (Opp. at 7.) Cephalon can advance this argument -- through cross-examination, by seeking to strike expert testimony, or by presenting its own expert testimony -- without any need for disclosure of the Third Parties' MMA and FTCA materials. Cephalon does not need the confidential MMA and FTCA materials to make the argument that the FTC cannot properly have its experts rely on advocacy studies prepared by the FTC, or to establish that the studies are not supported by evidence in the record.

In short, where disclosure would cause significant injury to the Third Parties, and where, as here, the need for production is marginal or non-existent since the materials at issue will not be in evidence, the balancing test established by the case law cuts strongly against disclosure because "the potential harm caused by production outweighs the benefit." *Mannington Mills*, 206 F.R.D. at 529; *accord Pansy*, 23 F.3d at 785-86.

CONCLUSION

For the foregoing reasons, as well as those set forth in the Third Parties' opening memorandum, the Court should enter a protective order barring the FTC from disclosing documents or other information that the Third Parties or their subsidiaries and affiliates have filed with the FTC under the MMA or the FTCA.

Respectfully submitted,

//s//

Timothy C. Hester
Peter J. Martinez
COVINGTON & BURLING LLP
1201 Pennsylvania Ave. NW
Washington, DC 20004
(202) 662-6000 (Telephone)
(202) 778-6291 (Fax)

Counsel for Astellas Pharma Inc. and Astellas Pharma US, Inc.
Counsel for AstraZeneca PLC
Counsel for Merck Sharp & Dohme Corp., formerly Merck & Co., Inc.

Jeffrey I. Weinberger
MUNGER, TOLLES, & OLSON LLP
355 South Grand Avenue
Los Angeles, CA 90071
(213) 683-9100 (Telephone)
(213) 683-5127 (Fax)

Counsel for Abbott Laboratories

Michelle H. Seagull
AXINN VELTROP HARKRIDER LLP
90 State House Square
Hartford, CT 06103
(860) 275-8100 (Telephone)
(860) 275-8101 (Fax)

Counsel for Actavis Group hf and Actavis Inc.
Counsel for URL Pharma, Inc.

James S. Trainor, Jr.
WHITE & CASE LLP
1155 Avenue of the Americas
New York, NY 10036
(212) 819-8200 (Telephone)
(212) 354-8113 (Fax)

Counsel for Almirall, S.A.

William A. Rakoczy
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard St., Suite 500
Chicago, IL 60654
(312) 222-6301 (Telephone)
(312) 222-6321 (Fax)

Counsel for Anchen Pharmaceuticals, Inc.
Counsel for Lupin Limited and Lupin Pharmaceuticals, Inc.

Phillip A. Proger
JONES DAY
51 Louisiana Ave. NW
Washington, DC 20001
(202) 879-3939 (Telephone)
(202) 626-1700 (Fax)

Counsel for Bayer Healthcare Pharmaceuticals Inc.
Counsel for Esai Inc.
Counsel for King Pharmaceuticals, Inc.

Michael Sennett
Pamela L. Taylor
JONES DAY
77 West Wacker
Chicago, IL 60601
(312) 782-3939 (Telephone)
(312) 782-8585 (Fax)

Counsel for Baxter Healthcare Corporation
Counsel for Ben Venue Laboratories, Inc.
Counsel for Boehringer Ingelheim Pharmaceuticals, Inc.
Counsel for Roxane Laboratories, Inc.

Richard J. Stark
CRAVATH, SWAINE & MOORE LLP
825 Eighth Avenue
New York, NY 10019
(212) 474-1000 (Telephone)
(212) 474-3700 (Fax)

Counsel for Bristol-Myers Squibb Company

George G. Gordon
DECHERT LLP
2929 Arch Street
Philadelphia, PA 19104
(215) 994-4000 (Telephone)
(215) 994-2222 (Fax)

Counsel for Endo Pharmaceuticals Holdings Inc.

Andrew J. Miller
BUDD LARNER P.C.
150 John F. Kennedy Parkway
Short Hills, NJ 07078
(973) 379-4800 (Telephone)
(973) 379-7734 (Fax)

Counsel for Dr. Reddy's Laboratories Inc.

Michael N. Sohn
DAVIS POLK & WARDWELL LLP
901 15th St. NW
Washington, DC 20005
(202) 962-7000 (Telephone)
(202) 962-7111 (Fax)

Counsel for Forest Laboratories, Inc.

Stephen B. Deutsch
Sarah Cooleybeck
James M. Flaherty, Jr.
FOLEY HOAG LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210
(617) 832-1000 (Telephone)
(617) 832-7000 (Fax)

Counsel for Fresenius Medical Care Holdings, Inc.

George S. Cary
Kathleen W. Bradish
CLEARY GOTTLIEB STEIN & HAMILTON LLP
2000 Pennsylvania Ave. NW
Washington, DC 20006
(202) 974-1500 (Telephone)
(202) 974-1999 (Fax)

Counsel for GlaxoSmithKline plc

Kenneth A. Letzler
ARNOLD & PORTER LLP
555 12th Street NW
Washington, DC 20004
(202) 942-5000 (Telephone)
(202) 942-5999 (Fax)

Counsel for Hoffmann-La Roche Inc.

Seth C. Silber
Creighton J. Macy
WILSON SONSINI GOODRICH & ROSATI
1700 K St. NW
Washington, DC 20006
(202) 973-8800 (Telephone)
(202) 973-8899 (Fax)

Counsel for Impax Laboratories, Inc.
Counsel for Wockhardt Limited
Counsel for Wockhardt USA LLC

Paul Yde
Jan Rybnicek
FRESHFIELDS BRUCKHAUS DERINGER US LLP
701 Pennsylvania Ave. NW, Suite 600
Washington, DC 20004
(202) 777-4500 (Telephone)
(202) 777-4555 (Fax)

Counsel for Johnson & Johnson

J. Mark Gidley
Eric Grannon
Noah A. Brumfield
WHITE & CASE LLP
701 13th St. NW
Washington, DC 20005
(202) 626-3600 (Telephone)
(202) 626-9355 (Fax)

Counsel for Paddock Laboratories, Inc.
Counsel for Sunovion Pharmaceuticals, Inc., formerly Sepracor, Inc.

Robert A. Milne
Ross E. Elfand
WHITE & CASE LLP
1155 Avenue of the Americas
New York, NY 10036
(212) 819-8200 (Telephone)
(212) 354-8113 (Fax)

Counsel for Novartis Corp.
Counsel for Novartis Pharmaceuticals Corp.

Michael F. Brockmeyer
FROMMER LAWRENCE & HAUG LLP
1667 K St. NW
Washington, DC 20006
(202) 292-1530 (Telephone)
(202) 292-1531 (Fax)

Counsel for Par Pharmaceuticals, Inc.
Counsel for Shire LLC
Counsel for Upsher-Smith Laboratories, Inc.

Mark S. Popofsky
Michael S. McFalls
ROPES & GRAY LLP
One Metro Center
700 12th St. NW, Suite 900
Washington, DC 20005
(202) 508-4600 (Telephone)
(202) 508-4650 (Fax)

Counsel for Pfizer Inc.

Claudia R. Higgins
KAYE SCHOLER LLP
901 15th St. NW
Washington, DC 20005
(202) 682-3500 (Telephone)
(202) 682-3580 (Fax)

Counsel for Purdue Pharma L.P.

Robert A. Milne
Ross E. Elfand
WHITE & CASE LLP
1155 Avenue of the Americas
New York, NY 10036
(212) 819-8200 (Telephone)
(212) 354-8113 (Fax)

Counsel for Sandoz Inc.

Steven C. Sunshine
Maria Raptis
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 New York Ave. NW
Washington, DC 20005
(202) 371-7000 (Telephone)
(202) 393-5760 (Fax)

Counsel for Watson Pharmaceuticals, Inc.

Helene Jaffe
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
(212) 310-8000 (Telephone)
(212) 310-8007 (Fax)

Counsel for sanofi-aventis US LLC

February 22, 2011

CERTIFICATE OF SERVICE

I hereby certify that, on the date set forth below, the foregoing Third-Party Pharmaceutical Companies' Reply in Support of Motion for Protective Order was made available for downloading and viewing through the Court's CM/ECF system, and that notice of this filing was sent to all counsel of record through the CM/ECF system.

Bradley S. Albert
Federal Trade Commission
600 Pennsylvania Ave. NW
Washington, DC 20580
1440 New York Ave. NW
Washington, DC 20005
(202) 326-3759
balbert@ftc.gov

Counsel for Plaintiff Federal Trade Commission

James C. Burling
Mark A. Ford
WILMER CUTLER PICKERING HALE & DORR LLP
60 State Street
Boston MA, 02109
(617) 526-6000 (Telephone)
(617) 526-5000 (Fax)
james.burling@wilmerhale.com
mark.ford@wilmerhale.com

Counsel for Defendant Cephalon, Inc.

//s///
Peter J. Martinez

Date: February 22, 2011